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ORIGINAL ARTICLE

The combined effect of short foot exercises and orthosis in symptomatic flexible flatfoot: a randomized controlled trial

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ABSTRACT

BACKGROUND: Flatfoot is a musculoskeletal problem associated with dysfunctional active and passive supporting structures of the normal foot curvature. Strengthening of the intrinsic foot muscles or using shoe orthosis are recommend treatment approaches. However, investigating the effect of combining both approaches is still warranted.
AIM: To examine the effect of applying short foot exercises (SFE) combined with shoe insole *versus* shoe insole alone on foot pressure measures, pain, function and navicular drop in individuals with symptomatic flexible flatfoot.
DESIGN: Prospective, active control, parallel-group, assessor-blinded, randomized controlled trial and intention-to-treat analysis.
SETTING: Outpatient physical therapy clinic of a university teaching hospital.
POPULATION: Forty participants with symptomatic flexible flatfoot.
METHODS: A six-week treatment protocol of SFE (three sets of 10 repetitions a day) in addition to shoe insole (eight hours a day) (experimental group, N.=20) or shoe insole only (eight hours a day) (control group, N.=20). Clinic visits were made at baseline and every two weeks for monitoring and follow-up. The static and dynamic foot area, force and pressure measures, pain, lower extremity function, and navicular drop were assessed at baseline and postintervention.
RESULTS: Forty participants joined the study and 37 (92.5%) completed the six-week intervention period. Foot pressure, pain and function showed a significant interaction (P=0.02 – <0.001) and time (P<0.001) effects with a non-significant group effect in favor of the experimental group. *Post-hoc* analysis revealed that the experimental group had lesser pain (P=0.002) and better function (P=0.03) than the control group at six weeks. Navicular drop decreased equally in both groups.
CONCLUSIONS: Implementation of shoe insole and SFE for six weeks improved pain and function and altered foot pressure distribution greater than shoe insole alone in patients with symptomatic flatfoot.
CLINICAL REHABILITATION IMPACT: Wearing shoe insole is an easy, but passive, treatment approach for a flatfoot problem. This study provided evidence regarding the added benefit of SFE. It is recommended that rehabilitation practitioners implement a comprehensive treatment protocol including both shoe insole and SFE for at least six weeks to achieve better results for their flatfoot patients.

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KEY WORDS: Orthotic devices; Foot; Muscles.

Feet are important supporting and load-transfer structures of the human body. With a uniquely intricate anatomical features, it is likely predisposed to variable musculoskeletal disorders as flatfoot (also known as pes planus). The flatfoot is a musculoskeletal syndrome in which the medial longitudinal arch (MLA) of the foot is lowered or flattened. It is attributable to a complexity of static and dynamic abnormalities.[1] Several predisposing factors are associated with this problem such as increased weight, foot injury and musculoskeletal disorders.[2, 3] Flatfoot has been reported to be linked with variable disorders of the lower extremity (LE) such as patellofemoral pain syndrome and medial tibial stress syndrome.[4, 5] Additionally, reports highlighted a significant relationship between abnormal foot posture and gait mechanics.[6, 7]

The MLA is maintained by variable active and passive structures. Passive structures include the plantar ligaments, tendons and fascia and the natural tarso-metatarsal locking mechanism. Active support is provided by the extrinsic muscles as the tibilalis posterior,[8] and the intrinsic foot muscles (IFM). The IFM including the abductor hallucis and the flexor hallucis brevis are exceptionally important for maintaining a normal foot posture.[9, 10] This is supported by the findings that showed increased navicular drop with limited IFM activity.[11] Additionally, previous reports have shown that people with flatfoot had atrophied IFM with smaller cross sections.[12, 13]

Different approaches have been successfully implemented to conservatively manage a flatfoot deformity. Shoe orthosis, either prefabricated or customized, significantly influenced plantar force and pressure distribution. When compared to shoe alone, shoe orthosis increased force in the midfoot region, reduced pressure values in the forefoot and suppressed the talocalcaneal eversion.[14-16] It may also improve the ankle joint angle and moment.[17] A recent study showed that arch-support insole shortened stance time and increased peak pressure of the big toe and metatarsals and contact area of the midfoot.[18]

Another effective approach to manage a flatfoot deformity is the strengthening exercises for foot muscles, known as the short foot exercises (SFE).[19] Studies have shown that strengthening the foot muscles could likely decrease navicular drop (ND)[20, 21] and improve arch height.[20] Exercises for the foot muscles could also impact its performance[20, 22] and, consequently, likely enhance functional balance and reach tasks.[23, 24] Furthermore, foot pain was reported to significantly decrease in response to foot muscles exercises.[25, 26] Similar effects were also reported in obese people with pes planus.[27] Regarding foot pressure distribution, active intervention in the form of foot muscles exercises was found to help correct the static foot alignment by improving the foot posture index score,[28, 29] increasing the maximum plantar force of the midfoot, and decreasing the maximum medial ground reaction force.[25, 30]

Studies that compared the impact of SFE and shoe orthosis or examined their combined effect in flatfoot condition are relatively few and showed inconsistent findings with different outcome variables of interest.[19, 21, 26] In a recent network meta-analysis study, only three studies compared the effect of implementing both exercises and shoe orthosis combined *versus* orthosis alone on pain and ND in participants with flatfoot.[31-33] The meta-analysis revealed that the combined application of the two treatment approaches did not affect ND, but would likely reduce pain greater than foot orthosis alone. However, the difference was negligible.[26] Additionally, none of these studies used mainly SFE to treat participants. Instead, they used general exercises for the foot and lower limb. Another systematic review reported that out of six studies that examined the impact of SFE on MLA, four reported improvement but with inconsistent methodology regarding the SFE protocol.[19] An important criticism of studies examining the effect of SFE in flatfoot was the use of asymptomatic participants, which may compromise the applicability of its findings.[21]

To the best of our knowledge, none of the previous studies examined the combined effect of SFE and foot orthosis on plantar pressure distribution in flatfoot. Therefore, the purpose of this study was to examine the added benefit of SFE to foot orthosis on plantar pressure, pain, function, and MLA in symptomatic flexible flatfoot.

Materials and methods

Ethical approval was obtained from the Institutional Review Board of Imam Abdulrahman Bin Faisal University (IRB-PGS-2018-3-184). This study complies with the Code of Ethics of the World Medical Association (Declaration of Helsinki), and it was registered at ClinicalTrials.gov (NCT04480177). This manuscript was prepared in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[34, 35]

Design

This study was a prospective, active control, parallel-group, assessor-blinded, randomized controlled trial. Participants were randomized at a 1:1 ratio to the two study groups: the experimental group (SFE & FO), which re-

ceived the SFE program and shoe insole, and the control group (FO), which received the shoe insole only. The study duration was six weeks. Data collection points were baseline and six weeks for all the outcome variables except the foot plantar pressure, which was recorded at baseline and two, four and six weeks.

Participants

Potential candidates from the outpatient clinic of Imam Abdulrahman Bin Faisal University (Dammam, Saudi Arabia) and local community in the eastern province of Saudi Arabia were invited *via* flyers and social media announcements. Subjects were recruited if they had flexible flatfoot and suffered painful feet and lower limb fatigue for at least three months before joining the study. To confirm a flexible flatfoot problem during physical examination, participants must have shown a positive result for the "too many toes" sign, the navicular drop test (NDT), and the foot toe raising test. Subjects were excluded if they had Body Mass Index (BMI)≥25, leg length discrepancy, foot trauma, pathological condition or surgery within the last six months, and history of wearing foot orthoses within the past two years. Eligible subjects signed a consent form after explanation of the study procedures and potential risk.

Procedures

Randomization, blinding and allocation concealment

Permuted block randomization was implemented with variable block sizes of 4 and 6. Randomization order was generated using the online service at www.sealedenvelope.com. An excel file containing the randomization sequence was centrally generated and password-protected by the principal investigator to ensure allocation concealment. The patient assignment was liaised to the treating therapist by means of remote communication. Both the outcome assessor and the study statistician were blinded to group allocation. The treating therapist and outcome assessor were certified physical therapist with 7-10 years of experience.

Intervention

Participants in the FO group were instructed to wear a commercial prefabricated shoe insole (MDH Co., Cracow, Poland) for eight hours per day for six weeks.[36] The insoles contained a medial longitudinal arch support, which raised the MLA for by about 1.8 cm (Figure 1). Participants in the SFE & FO group were similarly instructed to wear the shoe insole. Additionally, the therapist demonstrated the SFE procedures while giving verbal instructions. Participants were instructed to sit on an adjustable chair, placing their hips, knees, and ankles at 90 degrees. A towel was placed under the foot, and participants were instructed to pull and hold for 5 seconds the first metatarsal head toward the heel while avoiding bending their toes.[24] Participants were instructed to perform three sets of ten repetitions/minute with a one-minute rest between sets daily for six weeks as a home program. The exercises progressed from sitting to standing and finally to one leg stance position every two weeks.[20] Participants were requested to visit the clinic every two weeks for monitoring and follow-up on exercise adherence and progression. An illustrated exercise description manual and exercise adherence logbook were given to each participant to record the home program sets and encourage adherence.

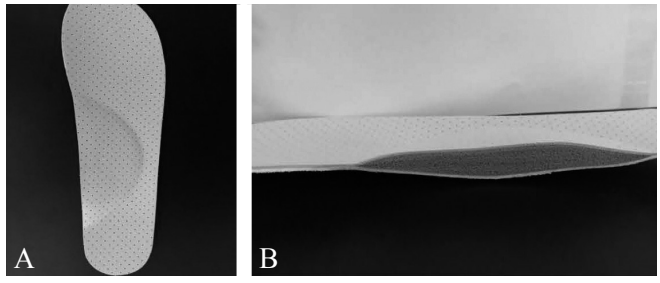

Figure 1.—Prefabricated shoe insole: A) top view; B) side view (medial longitudinal arch support).

Assessment of outcome measures

The study was conducted in the outpatient clinic of the physical therapy department in Imam Abdulrahman bin Faisal University. After signing the consent form by the participants, baseline assessment began by recording the participant's demographic data. The blinded assessor confirmed the flexible foot condition by assessing the "too many toes" sign, the foot toe raising test, and the NDT. Participants were instructed to assume a relaxed stand on both feet, while the examiner stood behind and observed the number of toes appearing towards the lateral aspect of the foot. A positive result occurs when more toes can be seen on the lateral side of each foot. Then, with the participant still standing, the examiner faced the participant and grasped the distal phalanx and dorsiflexed the big toe of each foot to check the toe raising test. A positive result was the reconstruction of the MLA.[37] For the NDT, the participant first assumed a sitting position with hips and knees at 90 degrees, and feet rested on the floor in a neutral position. The examiner marked the prominent navicular tuber-

osity. The height of navicular tuberosity from the floor was measured and marked on a card. The participant then was instructed to assume a relaxed full weight-bearing standing position, and the navicular tuberosity height was marked again on the card. A positive NDT is a navicular drop of ≥10 mm.[38] All examinations were performed bilaterally.

The primary outcome was the foot plantar pressure. The parameters assessed were the area of the foot and plantar force and pressure of both feet in static and dynamic conditions, which were recorded at baseline and at two-week intervals over the six-week course of the study. Data were measured using the EMED-X® system (novel GmbH, München, Germany). It is a system in which a matrix of capacitance-based sensors is integrated in a platform (700×403 mm) embedded into a seven-meter walkway. Data were recorded at a 100 Hz frequency. For the static measurements, participants were instructed to stand with feet at shoulder width and weight equally distributed on both feet. The assessed foot was placed on the center of the platform, and data were recorded for three seconds. For the dynamic conditions, a starting point was marked on the floor four meters from the EMED platform. Participants were instructed to walk barefoot at their normal preferred pace looking forward avoiding targeting the platform. Familiarization trials were performed before data recording. During the recorded trials, if participants targeted the platform, stepped outside the platform sensors area, or altered their pace, the trial was repeated. The average of three appropriately performed trials was calculated and used for data analysis.

Secondary outcomes were pain, function and navicular drop, which were assessed at baseline and the sixth week. Foot pain was assessed using the Arabic version of the Numeric Pain Rating Scale (ANPRS).[39] The ANPRS is a horizontal 11-point scale (0-10), with 0 indicating no pain and 10 indicating the worst pain ever. Participants were instructed to mark the score that they believed corresponds to their experienced pain level. The LE function was assessed by the Arabic version of the lower extremity function scale (LEFS-Ar), which is a reliable and valid tool to assess functional limitations of the LE.[40] The LEFS-Ar comprises 20 items, each scored on a 0-4 Likert Scale. Summing item scores yields a total score of 0-80. Higher score indicates better LE function. The navicular drop was assessed by the NDT.

Statistical analysis

The sample size was calculated using the GPower software (G-Power, Brunsbüttel, Germany) based on a mixed-effects ANOVA test for data analysis. According to foot pressure data from the literature,[15] sample size calculation with effect size of 0.6, power of 80%, significance level of 0.05, two study groups and four data collection points resulted in a required total sample size of 32 participants (16 participants per group). Accounting for an attrition rate of 20%, 20 participants were recruited per group.

The sample demographic characteristics were analyzed using the χ^2 statistics and independent-samples *t*-test. Data were presented using frequencies and percentages

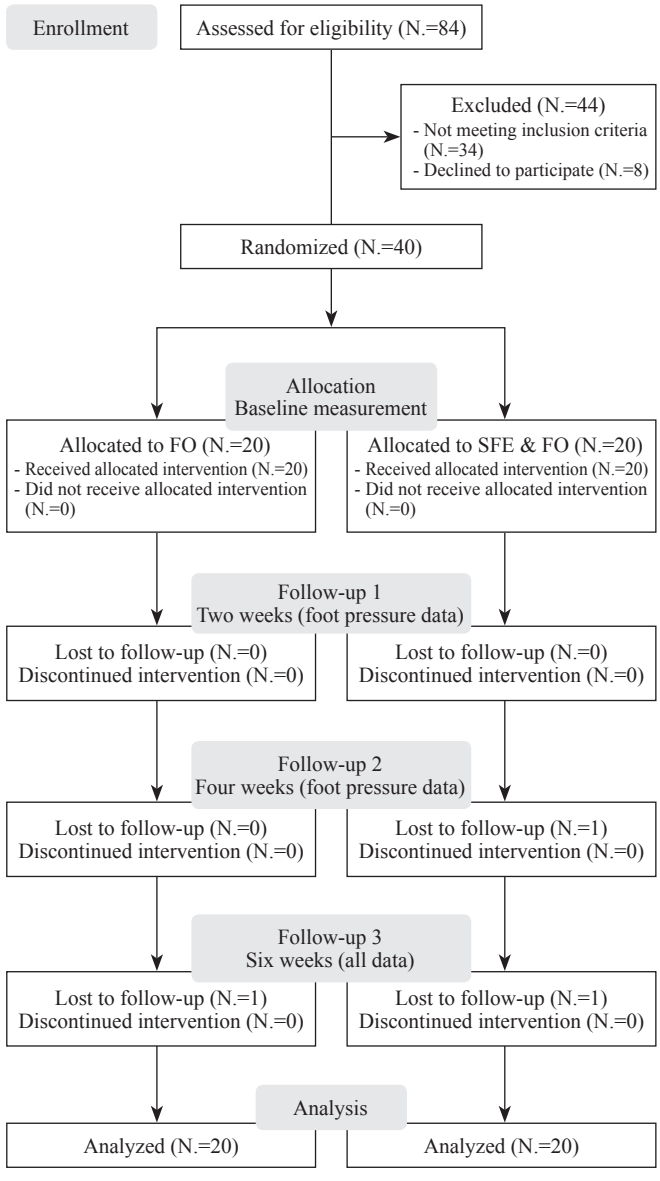

Figure 2.—Patients' flowchart.

TABLE I.—*Participants' demographic data and baseline measurements.*

Variables	FO (N.=20)	FO & SFE (N.=20)	P value
Age (y)	24.9 (4.7)	26.8 (6.5)	0.29
Gender			
Male	5 (25%)	7 (35%)	0.45
Female	15 (75%)	13 (65%)	0.55
Weight (kg)	62.5 (9.8)	65.7 (10.0)	0.31
Height (m)	1.63 (0.1)	1.68 (0.1)	0.06
BMI	23.3 (1.9)	23.1 (1.9)	0.71
Duration of foot pain (mo)	16.7 (7.5)	16.5 (8.6)	0.95
ANPRS score	6.0 (0.8)	6.1 (1.4)	0.69
LEFS-Ar score	59.5 (8.7)	58.8 (8.0)	0.81
NDT (cm)*	11.6 (1.6)	11.5 (1.5)	0.67
Area_static (cm^2)*	136.8 (22.6)	143.9 (17.4)	0.12
Force_static (N)*	755.1 (283.5)	767.9 (204.3)	0.82
Pressure_static (kPa)*	473.0 (145.8)	492.0 (139.3)	0.55
Area_dynamic (cm^2)*	144.3 (21.2)	149.0 (18.0)	0.29
Force_dynamic (N)*	816.4 (294.9)	838.3 (184.3)	0.79
Pressure_dynamic (kPa)*	739.6 (198.8)	696.0 (180.8)	0.31

Data reported as mean (standard deviation) or number (%).
*Data from both feet combined (N.=40).
y: year; kg: kilogram; m: meter; mo: months; d: days; h: hours; cm: centimeter; N: Newton; kPa: kilopascal.

or mean±standard deviation as appropriate. Mixed-effects ANOVA was used to test for significant interactions between the treatment arms across the within-subject observations of the outcomes. If significant interactions were detected, *post-hoc* pairwise comparisons using *t*-tests with Bonferroni adjustment were performed. Data were examined for normality using The Shapiro-Wilk's Test. Levene's Test was used to check the assumption of homogeneity of variance. All analyses were conducted using SPSS version 26 (IBM Corp, Armonk, NY, USA) and statistical significance was assumed at an alpha value of 0.05. The Intention to Treat (ITT) principle was adopted to handle missing data. Last observation carried forward method was implemented.

Results

Between January 2019 and July 2020, 84 patients with flexible flatfoot were screened for eligibility. Forty-four patients were excluded, and 40 participants were equally randomized to the FO (N.=20) and FO&SFE (N.=20) study groups (Figure 2). At the end of the study, 37 participants completed the six-week period of the study (19 FO and 18 FO&SFE; 92.5%). Data of all variables were homogenous and normally distributed. Participants' demographic characteristics and baseline measurements were not significantly different between the two groups (Table I). Adherence to the prescribed exercise protocol for the FO&SFE group was 34.4±4.8 days (81.9%). Shoe insole daily usage log revealed a cumulative adherence of 82.2% (276.1±49 hours) and 83.2% (279.4±41.2) for the FO and FO&SFE groups, respectively (P=0.83).

Primary outcomes

Static foot pressure showed a significant interaction (time and group) (P=0.02) and within-group (time) (P<0.001) effects. However, the between-group effect was not significant (P=0.14). *Post-hoc* analysis showed a significant within-group increase of pressure measures in the FO&SFE group (difference [Diff.]=79.7 kPa, Effect size [ES]=0.5; P<0.001), but not in the FO group. The FO&SFE group had higher pressure than the FO group at six weeks (Diff.=74.9 kPa, ES=0.45; P=0.047).

Similarly, dynamic foot pressure showed a significant interaction (P<0.001) and within-group (P<0.001) effects, but the between-group effect was insignificant (P=0.65). *Post-hoc* analysis showed a significant within-group increase of pressure measures in both the FO&SFE group (Diff.=186.2 kPa, ES=1.0; P<0.001), and FO group (Diff.=75.7 kPa, ES=0.40; P<0.001). The between-group pressure measures difference insignificantly increased at six weeks (Diff.=66.9 kPa, ES=0.34; P=0.13).

Overall, the static and dynamic foot area decreased slightly after the intervention. Both outcome measures did not show a significant interaction (P=0.39 and P=0.16, respectively) or group (P=0.16 and P=0.20, respectively) effects. However, the static area decreased significantly after the intervention (P<0.001), while the dynamic area did not significantly change (P=0.15). Further analysis confirmed a significant within group reduction of static foot area at six weeks in the FO&SFE (Diff.=-6.4 cm^2, ES=-0.39; P<0.001) and FO (Diff.=-3.9 cm^2, ES=-0.19; P=0.003) groups.

Regarding the foot force, both the static and dynamic conditions were affected by time only (P>0.001) without showing interaction (P=0.15 and P=0.46, respectively) or group (P=0.86 and P=0.60, respectively) effects. The study groups showed a significant, but small increase of static (FO&SFE: Diff.=30.5 N, ES=0.15; P<0.001; FO: Diff.=26.9 N, ES=0.09; P<0.001) and dynamic (FO&SFE: Diff.=38.7 N, ES=0.22; P<0.001; FO: Diff.=24.7 N, ES=0.08; P=0.02) force magnitude after intervention (Table II).

Secondary outcomes

According to the ANPRS reported data, foot pain had a significant interaction (P=0.03) and time main (P<0.001)

TABLE II.—*Primary outcome measures.*

Outcome measure	FO (N.=40 feet)	Within-group difference, (P)/ES	FO and SFE (N.=40 feet)	Within-group difference, (P)/ES	Between-group difference, (P)/ES
Area_static (cm^2)					
Baseline	136.8 (22.6)		143.9 (17.4)		
2 weeks	135.7 (20.5)	-1.2, (1.0)/-0.05	141.4 (17.6)	-2.6, (0.11)/-0.14	5.7, (0.18)/0.30
4 weeks	134.2 (18.5)	-2.6, (0.16)/-0.13	139.5 (14.7)	-4.4, (0.001)/-0.27	5.2, (0.16)/0.32
6 weeks	132.9 (19.0)	-3.9, (0.003)/-0.19	137.6 (14.9)	-6.4, (<0.001)/-0.39	4.6, (0.23)/0.28
Force_static (N)					
Baseline	755.1 (283.5)		767.9 (204.3)		
2 weeks	767.3 (298.6)	12.2, (0.11)/0.04	766.2 (202.5)	-1.8, (1.0)/-0.01	-1.2, (0.98)/-0.004
4 weeks	768.9 (299.6)	13.8, (0.11)/0.05	781.0 (196.1)	13.1, (0.15)/0.07	12.1, (0.83)/0.05
6 weeks	782.0 (297.2)	26.9, (<0.001)/0.09	798.5 (192.6)	30.5, (<0.001)/0.15	16.5, (0.77)/0.07
Pressure_static (kPa)*					
Baseline	473.0 (145.8)		492.0 (139.3)		
2 weeks	460.9 (157.3)	-12.1, (1.0)/-0.08	505.7 (132.4)	13.7 (1.0)/0.10	44.8, (0.17)/0.31
4 weeks	473.9 (157.2)	0.9, (1.0)/0.01	530.5 (159.6)	38.5 (0.07)/0.26	56.6, (0.11)/0.36
6 weeks	496.8 (156.2)	23.8 (0.27)/0.16	571.7 (176.0)	79.7 (<0.001)/0.50	74.9, (0.047)/0.45
Area_dynamic (cm^2)					
Baseline	144.3 (21.2)		148.9 (18.0)		
2 weeks	145.2 (22.8)	0.9, (1.0)/0.04	148.2 (17.3)	-0.8, (1.0)/-0.04	3.0, (0.51)/0.15
4 weeks	138 (21.0)	-6.1, (0.04)/-0.30	148.1 (17.3)	-0.9, (1.0)/-0.05	9.9, (0.02)/0.52
6 weeks	143.5 (24.4)	-0.77, (1.0)/-0.04	146.3 (16.3)	-2.7, (1.0)/-0.15	2.7, (0.56)/0.13
Force_dynamic (N)					
Baseline	816.4 (294.9)		838.3 (184.3)		
2 weeks	814.7 (296.0)	-1.7, (1.0)/-0.006	843.4 (181.8)	5.1, (1.0)/0.03	28.7, (0.69)/0.12
4 weeks	828.9 (300.0)	12.5, (0.25)/0.04	858.7 (179.0)	20.4, (0.007)/0.11	29.8, (0.60)/0.12
6 weeks	841.1 (308.4)	24.7, (0.02)/0.08	877.0 (171.9)	38.7, (<0.001)/0.22	35.9, (0.52)/0.14
Pressure_dynamic (kPa)*					
Baseline	739.6 (189.8)		696.0 (180.8)		
2 weeks	759.9 (199.6)	20.3, (0.9)/0.10	776.3 (185.3)	80.3, (<0.001)/0.44	16.4 (0.70)/0.09
4 weeks	783.2 (199.8)	43.6, (0.02)/0.22	817.9 (178.4)	121.9, (<0.001)/0.68	34.7 (0.42)/0.18
6 weeks	815.3 (191.8)	75.7, (<0.001)/0.40	882.2 (197.5)	186.2, (<0.001)/1.0	66.9 (0.13)/0.34

Mean (SD) at baseline and follow-up according to group. Within-group difference is calculated in reference to baseline measurement. Within-group ES (Cohen's *d*)= mean 2,4, or 6 week - mean baseline/SD_{pooled}. $SD_{pooled}=\sqrt{[(SD_1^2+SD_2^2)/2]}$. Between-group difference: mean FO & SFE - mean FO. Between-group ES (Cohen's *d*): mean FO & SFE - mean FO/pooled SD.
*Significant interaction effect at P<0.05
FO: foot orthosis; SFE: short foot exercise; SD: standard deviation; ES: effect size; cm: centimeter; N: Newton; kPa: kilopascal.

TABLE III.—*Secondary outcome measures.*

Outcome measure	FO (N.=80 feet)	Within-group difference, (P)/ES	FO&SFE (N.=80 feet)	Within-group difference, (P)/ES	Between-group difference, (P)/ES
Pain (ANPRS)*					
Baseline	6.0 (0.8)		6.1 (1.5)		
6 weeks	3.2 (1.0)	-2.8, (<0.001)/-3.1	2.3 (0.8)	-3.9, (<0.001)/-3.2	-0.95, (0.002)/-1.0
Function (LEFS-Ar) *					
Baseline	59.5 (8.7)		58.8 (8.0)		
6 weeks	66.9 (6.7)	7.5, (<0.001)/1.0	71.9 (7.1)	13.1, (<0.001)/1.7	5.0, (0.03)/0.72
Navicular drop (NDT)					
Baseline	11.6 (1.6)		11.5 (1.5)		
6 weeks	7.2 (1.6)	-4.5, (<0.001)/-2.7	6.5 (1.9)	-5.0, (<0.001)/-2.9	-0.65, (0.1)/-0.4

Mean (SD) at baseline and postintervention according to group. Within-group difference is calculated in reference to baseline measurement. Within-group ES (Cohen's *d*): mean 2,4, or 6 week - mean baseline/SD_{pooled}. $SD_{pooled}=\sqrt{[(SD_1^2+ SD_2^2)/2]}$. Between-group difference: mean FO & SFE - mean FO. Between-group ES (Cohen's *d*): mean FO & SFE - mean FO/pooled SD.
*Significant interaction at P<0.05.
FO: foot orthosis; SFE: short foot exercise; SD: standard deviation; ES: effect size; ANPRS: Arabic Numeric Pain Rating Scale; LEFS-Ar: Arabic version of the lower extremity function scale; NDT: Navicular Drop Test.

effects, but the group main (P=0.09) effect was not significant. The reported pain scores revealed that both the FO&SFE (Diff.=-3.9, ES=-3.2; P<0.001) and FO (Diff.=-2.8, ES=-3.1; P<0.001) groups showed a significant pain reduction postintervention. The decrease in pain level was significantly greater (Diff.=-0.95, ES=-1.0; P=0.002) in the FO&SFE than the FO group.

The LE function was not influenced by the group main (P=0.31) effect, but was significantly impacted by the time main (P<0.001) effect and the interaction (P=0.03) between time and group. Patients in both groups reported significantly better (FO&SFE: Diff.=13.1, ES=1.7; P<0.001; FO: Diff.=7.5, ES=1.0; P<0.001) LE function postintervention, but the improvement was significantly greater (Diff.=5.0, ES=0.72; P=0.03) in the FO&SFE than the FO group.

The NDT measures were significantly impacted by time only (P<0.001). The navicular drop was reduced after treatment in both groups (FO&SFE: Diff.=-5.0, ES=-2.9; P<0.001; FO: Diff.=-4.5, ES=-2.7; P<0.001), but the between-group difference was not significant (P=0.10) (Table III).

Discussion

The results of this randomized controlled trial demonstrate that the addition of SFE to shoe insole to treat symptomatic flexible flatfoot seems to effectively decrease foot pain, improve LE function and change static and dynamic foot pressure better than using shoe insole alone. While both treatment approaches significantly improved MLA support (decreased navicular drop), reduced foot contact area and increased force magnitude, no significant between-group difference was noticed. These findings indicate that SFE could likely impact foot pain and function in patients with flatfoot greater than other variables.

Analysis of the primary outcomes revealed that foot pressure magnitude generally increased after intervention in both groups. The FO&SFE group had the largest increase in pressure values, which increased by 26.8% and 16.2% with large (ES=1) and moderate (ES=0.5) effect sizes for the dynamic and static foot pressure, respectively. This can be explained in part by the increased foot force and decreased foot area that was recorded postintervention, which would typically increase the foot pressure values. Studies that assessed foot pressure in people with flatfoot are few and reported inconsistent findings. This makes comparison with previous literature difficult. Our results are in agreement with those of Aminian *et al.* who reported an increase in midfoot pressure with prefabricated insole.[15] In contrast, our results are inconsistent with other studies, which reported a reduction of midfoot pressure with shoe insole[16] or no change after SFE[25] or with arch-support insole.[18] It is important, though, to consider the methodological differences between the current and the previous studies to understand the discrepancy of findings. While most of them examined the impact of shoe insole,[15, 16, 18] only one study studied the effect of SFE,[25] and none investigated the combined effect of shoe insole and SFE. Unlike the current study, all the previous studies targeted asymptomatic flatfoot participants only. We believe that our sample of symptomatic flatfoot patients may likely be an important contributing factor to the disagreement with previous studies.

Despite not showing a significant interaction effect, foot force measures were significantly increased postintervention in both groups. Yet, the effect size was small (ES=0.2) even for the greatest force increase noticed (dynamic force for the FO&SFE group). Our findings are consistent with previous studies that showed increased midfoot force magnitude in response to wearing a prefabricated shoe insole[15] or implementation of a SFE program.[25] However, it is important to consider that the previous studies had a repeated-measures[15] or quasi-experimental (non-randomized)[25] designs. Similar findings were obtained for the static foot area measures only with moderate (ES=-0.39) effect size at best (FO&SFE group). It is apparent that both the shoe insole and SFE interventions may have a limited impact on the overall force and area measures in people with flatfoot. A potential reason for this is the methodological variability compared to the previous studies. Aside from the study of Unver *et al.*,[25] all the literature collected foot pressure, force or area data using an insole measurement system, while data of the current study were collected using a platform with participants walking or standing barefoot.

Pain was decreased postintervention in both groups with a very large effect size (ES around -3), and the improvement was significantly greater in the FO&SFE group with large between-group effect size (ES=-1). This comes in accordance with several previous studies, which assessed the impact of orthosis,[41, 42] exercise,[25, 43] or the combination of both[31-33] on pain in flatfoot. Unlike the current study, Andreasen *et al.*[31] reported a signifincat pain reduction postintervention that was similar between the study groups. According to their reported data, adherence of patients in the exercise groups to the treatment sessions was low as 70% of them recieved only one of two sessions per week during the 12-week study period. This may have limited

the effect of exercise treatment. Furthermore, there was a potential risk of cross-contamination between the exercise and orhtosis groups as some patients in the exercise groups used the shoe insole. These factors may explain the disagreement with the current study regarding the significant between-groups diffrence.

A recent network meta-analysis study revealed that active intervention including strengthening exercises with or without orhtosis have greater impact on pain releif than passive intervention in flatfoot.[26] The MLA is supported by both active (muscles) and passive (bones and ligaments) structures. In flatfoot, the arch is flattened and its construction collapses. This would impose excessive stresses on different foot structures leading to pain.[1] Accordingly, pain may further inhibit muscle activity and impair function.[44] Orthosis could maintain appropriate MLA structure and, thus, likely reduce abnormal stresses.[14] However, it would not enhance muscle activity. Strengthening of foot muscles could contribute further to break the chain by enhancing muscular support of foot structures and increase proprioceptive feedback.[44] Therefore, intervention protocols combining passive and active approachs could provide a superior pain releif effect.

In accordance with the literature,[25, 27, 33, 41] our findings revealed that function significantly improved after intervention for both groups with large effect sizes (ES=1 and 1.7 for the FO and FO&SFE groups, respectively). The improvement was greater for the FO&SFE group with moderate between-group effect size (ES=0.72). Limited function is associated with foot pain.[45, 46] Accordingly, LE function would be expected to improve with decreased foot pain, as was reported in the current study. Additionally, flatfoot condition seems to change the foot mechanical performance as a result of dysfunctional MLA and limited intrinsic muscle activity. Okamura *et al.* found that the SFE could improve foot posture and temporal parameter of the foot kinematics during gait.[30] The authors suggested that this indicates improved Windlass mechanism and, thus, foot functional performance. This could be further corroborated by the research reports demonstrating that SFE could improve static and dynamic balance in normal people[20, 23] and others with flatfoot.[24, 27]

Both the FO and FO&SFE groups showed similar effect on ND postintervention. The ND was significantly decreased with very large effect sizes (within-group ES=-2.7 and -2.9 for the FO and FO&SFE groups, respectively). This finding agrees with the majority of the literature. Exercises, particularly SFE, and orthosis have been shown to decrease ND in people with[24, 25, 27, 29] or even without[20] flatfoot. In contrast, some literature reported contradicting findings. Lynn *et al.* reported insignificant reduction of ND after SFE.[23] However, the authors ran their RCT on normal participants without flatfoot. Hoang *et al.* conducted a network meta-analysis study that included 10 RCTs and reported that neither active (exercises or exercises with orthosis) nor passive (orthosis only) intervention was found to affect ND.[26] A recent literature review reported that RCTs that examined the effect of SFE on ND all suffered high risk of bias and several methodological issues. They also concluded that SFE could reduce ND with an intervention period longer than five weeks, which was not uniform across the different studies.[19] It appears that the effect of SFE and/or orthosis on ND could be variable depending on the targeted sample criteria and intervention procedures. Therefore, a logically sound argument would be that there is acceptable supporting evidence that SFE and orthosis could improve ND. Yet, the strength of their effect is dependent upon the treatment protocol and the patient's criteria.

Limitations of the study

The current study had some limitations. The long-term effect was not assessed, which could have provided in-depth information regarding the longevity of the impact the combined application of the SFE, and orthosis could likely have on MLA and LE pain and function. Another limitation is the lack of foot masking into different regions as the software used for data analysis did not have the masking feature. This limited our ability to assess the foot area, force and pressure data in the different foot region independently.

Conclusions

Implementation of a comprehensive treatment approach that comprises strengthening of internal foot muscles (SFE) and shoe insole, which is more pragmatic, would significantly decrease pain and improve function of patients with symptomatic flatfoot. Clinicians treating patients with symptomatic flatfoot are encouraged to adopt a multimodal management strategy that combines both active and passive intervention techniques for at least five weeks to achieve better outcomes.

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